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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/768,760
Filing Date: January 29, 2004
Appellant(s): MINH MINER ET AL.

Edward M. Weisz
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/21/2009 and the correction filed 1/27/2010 appealing from the Office action mailed 8/3/2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the revised brief filed 1/27/2010 is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 6-10, 13, 15-21, 23-26, 28, 30-36, 38-42, 49 and 51 rejected under 35 U.S.C. 103(a) as being unpatentable over Bormann et al (6,336,916) in view of Darling, Jr (6,213,986).

a. Regarding claim 1, Bormann discloses an IV-solution delivery system comprising a coupling assembly having an input 210 and output 300 for coupling to the container 200 to provide flow of the solution through the coupling assembly to the output 220. A drip chamber 100 (figure 6) is shown in detail in figure 1. The drip chamber 100 has a top wall, bottom wall and a side wall 16/18, an input 1 and output 2. Input 1 couples to the coupling assembly (see figure 6) to receive solution drops formed from the flow of the solution to form a reservoir in the drip chamber. The side wall 16/18 has an opening located between the top and bottom walls, with a vent plug 10 covering the opening. The vent plug allowing air contained in the drip chamber which becomes displaced upon formation of the reservoir to be escape from the drip chamber through the vent plug. A patient conduit 230 is coupled to the drip chamber outlet (figure 6). The conduit 230 has a flow restriction device 400' capable of restricting the flow of air and liquid in the patient conduit (on/off) to allow the reservoir to achieve a level at least equal to the height of the vent plug while air (and liquid) in the patient conduit is expelled from the termination end. Wetting of the vent plug 10 prevents the entry of air

through the vent plug to the drip chamber and prevents the exit of solution from the drip chamber through the vent plug (Col.2 lines 61-64).

While Bormann substantially discloses the apparatus as claimed, it does not disclose the opening in the side wall of the drip chamber as forcing the air out in a direction transverse to the drip flow. Also, while Bormann is drawn to a drip chamber it never specifically states the sidewalls as being clear or transparent.

However, Darling also discloses a drip chamber apparatus, including a drip chamber 36 with a horizontal vent tube 94 with micropore filter element 96. The vent is disclosed as venting the lower chamber to atmosphere while maintaining sterility of the chamber (Col.8 lines 1-6). Darling also discloses the side wall is constructed of a transparent material so the interior/flow through the drip chamber may be seen from outside the device (Col.5 lines 28-32). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the drip chamber of Bormann by placing the vent in a horizontal direction (perpendicular to the flow of the solution through the drip chamber) as taught by Darling as it is a known placement within the drip chamber art for an air vent and there would be only the expectation of success of venting air to the atmosphere while maintaining the sterility of the drip chamber. Finally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the drip chamber of Darling by making sure the sidewalls were transparent as is both notoriously well known within the drip chamber art and taught by Darling in order to allow an operator to see into the drip chamber.

b. Regarding claim 6, flexible conduit 220 couples the coupling assembly output to the drip chamber and has a length such that the two may be separated so the drip chamber is capable of being positioned in close proximity to a patient and provide minimal disturbance of the coupling assembly.

c. Regarding claim 7, drip orifice 23 is located in the drip chamber top wall for forming solution drops.

d. Regarding claims 8, 35 and 42, while Bormann substantially discloses the apparatus as claimed, it does not disclose the opening coinciding with 1/3 of the total volume of the drip chamber. However, Bormann does disclose the side vents allowing the level to be filled to a predetermined level less than the total capacity of the housing. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to place the sidewall aperture of Bormann at a location such that the reservoir occupies 1/3 of the volume of the drip chamber because Applicant has not disclosed that utilizing only 1/3 of the volume of the drip chamber provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well as the drip chamber disclosed by Bormann. Therefore, it would have been an obvious matter of design choice to modify Ford to obtain the invention as specified in claim 8.

e. Regarding claim 9, vent plug 10 comprises an absorbing material and a housing 10a/10b connected to the side wall opening and defining a cavity for

receiving a formation of the absorbent material, where the absorbing material is a super-absorbent polymer that expands in response to wetting by the reservoir (Col. 3 lines 17-22).

f. Regarding claim 10, see claim 12 above.

g. Regarding claim 13, the surrounding cylinder of port 4 is a cannula with a cavity 4, with the absorbing material within. The cannula is secured to the sidewall opening has a first end in communication with the drip chamber and a second end in communication with the surrounding atmosphere.

h. Regarding claims 15 and 30, Bormann discloses meshes or screens to support the absorbent material (Col.7 lines 36-39). Bormann does not disclose expressly a trapezoidal housing cavity. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to give the housing cavity a trapezoidal cross-section because Applicant has not disclosed that a trapezoidal shaped cavity provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with Bormann because both shapes of the cavities will retain the vent plug. Therefore, it would have been an obvious matter of design choice to modify Bormann to obtain the invention as specified in claim 15.

i. Regarding claim 16, Bormann discloses a conduit 210 for connecting to supply container 200. Bormann further discloses a "spike" for connecting the conduit to the container (Col.5 lines 47-50)

j. Regarding claim 17, Bormann discloses an additional venting means 101 for venting gas (Col.5 lines 55-60), the conduit is closable via control device 400.

k. Regarding claim 18, the conduit connected to coupling 1 will assume a funnel shape as it frictionally engages the coupling and will direct solution from the container to the drip chamber.

l. Regarding claims 19 and 20, While Bormann substantially discloses the apparatus as claimed including an air filter 101 above the interfacing area to allow trapped air in the coupling member to escape, it does not disclose a membrane in the funnel portion to prevent air from entering the drip chamber. However, It would have been obvious to one of ordinary skill in the art at the time the invention was made to move the filter (which includes a hydrophilic absorbent membrane of Bormann) to the end of the coupling assembly line (interfacing area) since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse,* 86 USPQ 70 and forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893)

m. Regarding claim 21, the drip forming portion 22 may be considered part of the coupling member to form the solution into drops.

n. Regarding claim 23, see figure 2 which shows a shield 24 connected to the side wall above the vent plug and extending across the vent plug.

o. Regarding claim 24, see claim 1 above. The opening is formed in the side wall between the top and bottom walls and a vent plug covers the opening, the

vent plug comprised of a material allowing air to escape and restricting the flow of air once wetted. (Col.3 lines 15-22).

p. Regarding claims 25 and 26, see claim 9 above.

q. Regarding claim 28, see claim 13 above.

r. Regarding claim 31, see claim 1 above regarding the drip chamber.

s. Regarding claims 32, 34 and 36, see claim 9 above.

t. Regarding claim 33, see figures 1 and 2, which show the vent plug is a ring/band of material comprising an absorbing material and disposed over the opening in the side wall.

u. Regarding claim 39, see claim 23 above.

v. Regarding claim 40, see claim 1 above. The first material is disclosed as being impervious (Col.7 lines 45-47). The second material is the absorbing material addressed above.

w. Regarding claim 41, see claim 9 above.

x. Regarding claim 49, see claim 1 above, also see Col.10 lines 1-13. Bormann does not specifically disclose the container being at a height above the patient. However, this must occur because the principles upon which drip chambers and IV bags depend on the difference in height between the patient and IV bag to generate a pressure gradient. (hydrostatic pressure).

y. Regarding claim 51, see clamps 400/400'.

Claims 2-5, 43-48, 50, and 52-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bormann et al (6,336,916) and Darling, Jr (6,213,986) as applied to claims 1 and 49 above, and further in view of Knighton (4,571,244).

z. Regarding claims 2 and 3, Bormann discloses additional filters (such as 101) for eliminating gas. While Bormann substantially discloses the apparatus as claimed, it does not disclose a termination end cap with a vent for allowing gas present in the patient conduit to be eliminated through the end cap while preventing leakage of the solution. However, Knighton is drawn to a system for removing gas bubble from liquids. Knighton specifically states, *"The system is inexpensive and simple to use. A nurse or doctor merely inserts the device into the IV line. Entrapped gas flows out of the chamber through the second gas-passing filter, the gas-free fluid flows through the first fluid-passing filter into the patient." (Col.1 lines 66-68 to Col.2 lines 1-2)* Therefore it would have been obvious to one of ordinary skill in the art to add the gas expelling device of Knighton to the end of the patient conduit of Bormann in order to further expel gas in order to avoid a gas embolism in the patient.

aa. Regarding claim 4, the end plug of Knighton utilizes a hydrophilic porous material (Col.2 line 46)

bb. Regarding claim 5, The flow restriction device 400' is disclosed as possibly being a clamp. (Col.5 line 45) which selectively closes the patient conduit to isolate the patent from the drip chamber.

cc. Regarding claim 43, see claims 1 and 2 above.

dd. Regarding claim 44, the device of Knighton is releasably attachable to the termination end (Col.1 lines 66-67).

ee. Regarding claim 45, a luer connection is notoriously well known within the art as a way of reversibly sealing medical devices together.

ff. Regarding claim 46, the end vent plug also has a hydrophobic material (Col.2 lines 48-49).

gg. Regarding claim 47, Bormann discloses the regulating means as drip chamber 100.

hh. Regarding claim 48, Bormann discloses the regulating means is also a pump in that it uses gravity to generate a pressure gradient to pump fluid into a patient.

ii. Regarding claim 50, see claim 2 above and citation in claim 44.

jj. Regarding claim 52, see claim 1 above.

kk. Regarding claim 53, see claim 1 above.

ll. Regarding claim 54, the termination end cap is capable of allowing air to escape from the line and formation of the reservoir.

mm. Regarding claim 55, see claim 1 above. The hydrophilic filter discussed above will seal upon wetting to prevent air from further exiting through that route.

Claims 11, 12, 14, 27, 29, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bormann et al (6,336,916) and Darling, Jr (6,213,986) as applied to claims 1, 24, 25 and 32 above, and further in view of Bucevschi et al (6,833,488).

nn. Regarding claim 11, Bormann discloses housings 10b in communication with the drip chamber and a second end 10a in communication with the atmosphere. The cavity receiving the absorbing material 10 (see claim 9). Bormann further discloses the device may have additional components including vents (Col.5 line 58). Also disclosed is a liquophobic portion as part of porous medium 10, which will not absorb/expand with water and acts as a filter at the first end (Col.6 lines 35-36). 10b passes gas as well and acts a venting membrane (Col.6 lines 36-37). While Bormann substantially discloses the apparatus as claimed, it does not disclose the polymer material in granular form. However, Bucevschi discloses absorbing materials are polymer based and can be presented in a variety of forms, including powder, granule, microparticle, film or fiber. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the absorbing structure of Bormann of a granules as taught by Bucevschi because it is a known form for absorbent polymers and there would be only the expectation of success of providing a different form for the absorbent structure.

oo. Regarding claim 12, it would have been obvious to one of ordinary skill in the art at the time the invention was made to give the vent plug anti-bacterial properties, as it would be art recognized as a location that bacteria could enter the IV system (even with a pour size of 5 micrometers as Bormann et al teaches) and then be introduced directly into the bloodstream of the patient, and using an anti-bacterial is notoriously well known to prevent this.

pp. Regarding claims 14 and 29, while Bormann substantially discloses the apparatus as claimed, it does not disclose a rigid impervious core in the absorbing material. However, Bormann discloses the invention may include additional layers or elements such as spacers and supports (Col.7 lines 37-40) and projections/ribs from the housing may interact directly with the porous material. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to project a projecting/rib into the center of the porous medium of Bormann to further support the porous material as taught by Bormann. An additional advantage would be the decrease in super absorbent materials would decrease the cost of the device.

qq. Regarding claim 27, see claim 11 above.

rr. Regarding claim 37, see claim 11 above.

ss. Regarding claim 38, see claim 15 above.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bormann et al (6,336,916) and Darling, Jr (6,213,986) in view of Meisch (4,465,479).

tt. Regarding claim 22, see claim 1 regarding the coupling assembly, drip chamber and patient conduit. While Bormann substantially discloses the apparatus as claimed, it does not disclose a splash guard for the vent plug. However, Meisch discloses an annular, conical splash guard for a drip chamber to protect the filter vents against gross or excessive splashing. Therefore, it would have been obvious to one of ordinary skill in the art at the time the

invention was made to provide air vents for the vent plug as taught by Meisch to the filter of Bormann to protect against gross or excessive splashing.

(10) Response to Argument

With respect to claims 1-42 and 47-55, Applicant argues that since Bormann stresses the ability to observe the rate of flow that it has already determined the best position of the venting gas passageway and would arrive at two conclusions: the user has to sacrifice observability from a direction and the outlet has be placed above the level of the reservoir. The Examiner does not believe that such is necessarily derived from the claims, especially in view of Darling, Jr. The Examiner disagrees that one considering both references as a whole would be lead away from the claimed invention. The Examiner dose not disagree that Darling, Jr. operates in a different way compared to Bormann. However, it is still a drip chamber and clearly indicates that venting gas in a direction transverse to the drip flow through the chamber is successful. One of ordinary skill in the art would recognize that venting in a transverse direction is not dependent on the presence of every other structure of Darling Jr.

Applicant argues that one of ordinary skill in the art at the time of the invention is guided only by the references, and must accept what is in the references. In this instance, the references guide one of ordinary skill in the art to the claimed invention. Applicant insists that an “opening that vents air to the exterior of the system on the side wall of the drip chamber at the location that corresponds to the desired height of the solution reservoir” is not present. This is interpretable two ways, the exterior of the system is the inlet to the air passageway, in which case Bormann shows this. Another

interpretation is that the outlet of the air passageway has to be at the height of the solution reservoir, in which case such is not claimed currently, but is rendered obvious by Darling Jr regardless since Bormann already teaches the opening to the air passageway at the height of the solution reservoir and Darling discloses venting may occur transversely.

Applicant argues that the Examiner has no support for the placement and orientation of the opening and vent plug being obvious. The Examiner believes support is present in the rejections themselves.

With respect to claims 43-48, 52 and 53, Applicant argues that Knighton fails to rectify the shortcomings of Bormann and Darling Jr, namely that of a wettable, sealable end vent plug to permit automatic priming of the conduit line. Applicant points to filters 26 and 28 and argues they are never sealed. The Examiner points to Knighton Col.1 lines 66-68 and Col.2 lines 1 and 2 to show that one side of Knighton seals against air leaving via that side and the other seals against liquid leaving that side. Knighton thus discloses two vents, one of which (the one that allows air but not fluid flow) that allows air displaced by the flow of solution through the patient conduit to escape the termination end and prevents the escape of solution though said vent of said termination end cap upon wetting of the end vent plug by the solution.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Bradley J Osinski/

Examiner, Art Unit 3767

Conferees:

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767

/Greg Vidovich/

TQAS, TC 3700